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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,064	04/27/2001	Veronique Gruber	18433/2002	1669

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,064	GRUBER ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24,56 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24 and 56* is/are rejected.

7)☒ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 17-24, 56 and 57 are pending in the application.

This Office Action is in response to the Amendment filed on 5/3/04.

Response to Amendment

The objection to claim 19 has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claims 19-24 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

Claims 17-24 and newly added claim 56 stand rejected under 35 U.S.C.103(a) for reasons set forth of the record mailed on 3/12/03 and further discussed below.

Claim 57 is objected to for reasons discussed below.

Claims 19-24 are rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

The priority documents are not present in the application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-24 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomashow et al. (6,417428), in view of Valla et al (1991, plasmid. Vol 25, pages 131-136).

In response to this rejection, Applicant asserts that Thomashow et al. chooses to use an Agrobacterium strain comprising a shuttle vector expressing trfA to achieve the purpose of replicating pMEN020 rather than cloning trfA gene expressed from the same vector. Applicant further asserts that the teaching of Valla et al. does indicate how to construct a binary vector that functions in plant. Applicant thus argues that neither Thomashow et al. or Valla et al. teaches or suggests a single vector containing both trfA locus and T-DNA. Furthermore, Applicant argues that there is no motivation to combine the references. Applicant argues that Thomashow et al. does not provide such motivation because the successful application of pMEN020 as a plant binary vector with the assistance of the well characterized Agrobaterium strain carrying a shuttle vector expressing trfA would only reduce the desire of one skilled in the art to make a binary vector carrying trfA gene itself. Moreover, Applicant argues that there is no expectation of success in making a replicable binary vector by replacing the helper strain used in Thomashow et al. with a trfA gene cloned onto the same binary vector. Applicant argues that neither Thomashow et al. nor Valla et al. teach whether trfA gene alone would be sufficient to make the vector replicable. Lastly, Applicant argues that absent from the disclosure of the instant application, there is no basis to assume that by cloning trfA gene onto a binary vector would achieve same function that the helper strain used in Thomashow et al. could achieve, and there would be no reasonable success to use the present invention as claimed. Applicant thus concludes that the invention is not obvious in view of the prior art.

These arguments has been fully considered but deemed unpersuasive. The teachings of Thomashow et al. and Valla et al. and the reasons for obviousness of the claimed invention were discussed in detail in the previous office action mailed on 3/12/03. In response to applicant's

arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, it is the combination of the teaching of Thomashow et al. and Valla et al. renders the claims obvious, rather than each reference alone. As such, Thomashow et al. and Valla et al. do not have to teach the claimed vector individually.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine is provided mostly by Valla et al., who teaches that the temperature sensitive phenotype is influenced by copy number of the trfA transcripts, wherein the cis vectors are low copy number and trans vectors are high copy number (abstract). Therefore, manipulating the vectors comprising trfA in cis position or trans position can change the activity of temperature sensitive expression of trfA, thus providing a tool for modulating expression of the trfA expression. Although this motivation is different from Applicant's motivation for making the claimed vector, the statue does not require the references to provide the same motivation as the Applicant's for making the obviousness rejection. Whether the teaching of Thomashow et al. demonstrates successful application of pMEN020 as a plant binary vector with the assistance of the well characterized Agrobacterium strain carrying a

shuttle vector expressing trfA does not exclude one of ordinary skill in the art to make modification to the vector as long as there is a motivation for doing so. As such, contrary to Applicant's assertion, the teaching of the Valla reference does provide a motivation to combine the references to reach the claimed invention.

In response to applicant's argument that there is no reasonable expectation of success, the examiner does not agree that the combined teaching does not provide such expectation. Thomashow et al. teach that the helper strain, the ABI Agrobacterium carries a modified defective Ti plasmid that serves as a helper plasmid that containing a complete set of vir genes and trfA gene functions that are required for autonomous replication of the binary vectors after transplant into ABI strain. Although Thomashow et al. do not teach whether other factors are needed for the successful replication of the binary vector pMEN020, the required elements disclosed in this references are same as the claimed invention. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to insert the trfA gene to the binary vector taught by Thomashow et al. to make the claimed binary vector. This vector does not have to have the same function as the vector taught by Thomashow et al. since this is not a limitation of the instant claim. Likewise, the intended use of the claimed vector is not a limitation of the claim that would alter the structure of the claimed vector. Therefore, the combined teaching of Thomashow and Valla renders the claimed invention *prima facie* obvious, and this rejection is maintained.

Claim 56 is drawn to a synthetic vector comprising a nucleic acid sequence coding for a first origin of replication; a nucleic acid coding for a selection agent; a trfA locus coding for a protein that permits an increase in the replication rate of the vector; and a nucleic acid sequence

encoding for a T-DNA, including a right border, and a left border, which permits the vector to function as a binary plasmid, wherein the nucleic acid sequence coding for a selection agent is located near the left border of the T-DNA.

Applicant argues that the combined teaching of Thomashow and Valla does not teach the limitation of the nucleic acid coding for a selection agent is located near the left border of the T-DNA.

This argument is considered unpersuasive. Applicant's attention is directed to col. 27, lines 51-53, which teaches the arrangement of the nucleic acid sequence segments of the pMEM020 vector. It demonstrates in a counterclockwise direction on a map, the vector comprises "ori-V, left border, chimeric gene used as selectable marker, CaMV 35S promoter and E9 3' region gene cassette and restriction sites for inserting genes such as the coding region of CBF genes and ends with E9 3' region from the pea small subunit of RUBISCO gene and right border of T-DNA." According to this disclosure, it is apparent that the nucleic acid sequence coding for a selection agent is located near the left border of the T-DNA, rather than right border of the T-DNA. Therefore, for reasons discussed in the previous office action and above, claim 56 is obvious in view of the combined teaching of Thomashow et al. and Valla et al.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Objections

Claim 57 is objected to for containing non-elected subject matter. Applicant has elected SEQ ID NO:10 for examination. Amending the claims such that they are only directed to elected inventions is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "nucleic acid sequence corresponding to" in claim 19 renders the claim indefinite because it is unclear whether the nucleic acid sequence is a promoter/terminator, or just sharing sequence homology with a promoter/terminator. Further, it is unclear which part the of the promoter/terminator such nucleic acid is "corresponding" to. As such, the metes and bounds of the claim cannot be established. Claims 20-24 are rejected for same reason because they depend on claim 19.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 9/3/1999. It is noted, however, that applicant has not filed a certified copy of the 99111112 application as required by 35 U.S.C. 119(b). In addition, the PCT/IB00/01243 is also missing.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.
CELIAN QIAN
PATENT EXAMINER